## IAPOREC'APCTAPTO 22 DEC 2006

## PATENT APPLICATION

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91103

Harumi MINEKAWA, et al.

Appln. No.: Unassigned

(§371 entry of PCT/JP2004/008355)

Confirmation No.: Unassigned Group Art Unit: Unassigned

Filed: December 22, 2005 Examiner: Unassigned

For: METHOD FOR DETECTING SARS CORONAVIRUS

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

Applicants meet the requirements for a concise explanation of foreign language documents under 37 C.F.R. § 1.98(a)(3) in the following manners. First, Applicants enclose herewith a copy of the International Search Report, indicating the degree of relevance of each

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INFORMATION DISCLOSURE STATEMENT §371 entry of PCT/JP2004/008355

Q91103

document. Additionally, EP 1020534 A1 (document (3)) and EP 1327679 A1 (document (4)) are enclosed, which are English language versions of WO 00/28082 A1 (document (1)) and WO 02/24902 A1 (document (2)), respectively. Further, English language translations of documents (7), (9) and (12) are being submitted herewith, as well as English language abstracts of documents (11), (16) and (18).

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

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CUSTOMER NUMBER

Drew Hissong

Registration No. 44,765

Date: December 22, 2005

MODIFIED PTO/SB/08 A & B (06-03)

Substitute for Form 1449 A & B/PTO	IAP9 REC'DITARIO. 2 2 DEC 200			
Substitute for Form 1775 / La Dr. 10	Application Number	§371 entry PCT/JP2004/008355		
INFORMATION DISCLOSURE	Confirmation Number	Unknown		
STATEMENT BY APPLICANT	Filing Date	December 22, 2005		
	First Named Inventor	Harumi MINEKAWA		
(use as many sheets as necessary)	Art Unit	Unknown		
	Examiner Name	Unknown		
Sheet 1 of 2	Attorney Docket Number	O91103		

			U.S.	PATENT DOCUM	MENTS
		Document No	ımber		
Examiner Initials*	Cite No. <sup>1</sup>	Number	Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US			

FOREIGN PATENT DOCUMENTS								
Examiner Cite	Cite	Foreign Patent Document			Publication Date	Name of Patentee or		
Initials*	No.1	Country Code <sup>3</sup>	Number⁴	Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation <sup>6</sup>	
	(1)	WO	00/28082	A1	05-18-2000	Eiken Chemical Co., Ltd		
	(2)	WO	02/24902	• A1	03-28-2002	Eiken Chemical Co., Ltd		
	(3)	EP	1020534	A1	07-19-2000	Eiken Chemical Co., Ltd		
	(4)	EP	1327679	A1	07-16-2003	Eiken Chemical Co., Ltd		
	(5)	CN	1458281	A	11-26-2003	HUANQIU ZHONGJIA BIOLOG SCIENC	Abstract	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
	(6)	The World Health Organization Update 49-SARS case fatality ratio, incubation period, May 7, 2003, Case fatality ratio (date of search: June 24, 2003), URL: http://www.who.int/csr/sars/archive/2003_05_07/a/en	
	(7)	"SARS: Diagnostic test methods" (April 29, Revision 4-1), date of search: June 24, 2003, URL: http://idsc.nih.go.jp/others/urgent/update41-No.1html, the Infectious Disease Surveillance Center (IDSC), the National Institute of Infectious Diseases	Yes
	(8)	C. Drosten, et al., "Identification of a Novel Coronavirus in Patients with Severe Acute Respiratory Syndrome", N. England J. Med. May 15, 2003, Vol. 348, No. 20, pp 1967-1976	
	(9)	"SARS coronavirus gene gene detection using an RT-PCR method" (date of renewal: May 16, 2003), date of search: June 24, 2003, URL: http://idsc.nih.go.jp/others/urgent/update56-b.html, the Laboratory of Influenza Viruses, Department of Virology III, the Infectious Disease Surveillance Center (IDSC), the National Institute of Infectious Diseases	Yes
	(10)	T. Notomi, et al, "Loop-mediated isothermal amplification of DNA., Nucleic Acids Research, (2000), Vol. 28, No. 12, pagee 63 (i-vii)	
	(11)	J. Yang, et al., "Clinical Detection of polymerase gene of SARS-associated coronavirus", Journal of First Military Medical University, Department of Infectious Diseases, Nanfang Hospital, China, May 2003, Vol. 23, No. 5, pp. 424-427	Abstract
	(12)	Eiken Chemical Co., Ltd. "Eiken Kagaku, LAMP-ho o Riyo Shita SARS Corona Virus Kenshutsu Shiyaku Kaihatsu de Nagaski Daigaku Nettai Igaku Kenkyusho to Kyodo Kenkyu o Kaishi.", [online], June 19, 2003, [retrieved on August 3, 2004], retrieved from the Internet: <url: http:="" japanese="" sars_news_release.pdf="" www.tm.nagasaki-u.ac.jp=""></url:>	Yes
	(13)	GeneBank NC_004718.3, June 23, 2003, M.A. MARRA, et al., SARS coronavirus, complete genome, [retrieved on August 3, 2004], Retrieved from the Internet: <url: entrez="" http:="" viewer.fcgi?30271926:old12:897150="" www.ncbi.nlm.nih.gov=""></url:>	

	/Christopher Babic/		04/14/2008
Examiner Signature	'	Date Considered	

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached.

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MODIFIED PTO/SB/08 A & B (06-03)

				IAPO Rec'n Pi	CT/PTA 22 DEC 2004
Substitute for Form 1449 A & B/PTO	Com	Dete if Known			
		Application Number	Based on PCT/JP2004/008355		
INFORMATION DISCLOSURE			<u>URE</u>	Confirmation Number	Unknown
STAT	EMENT B	Y APPLIC	ANT	Filing Date	December 22, 2005
				First Named Inventor	Harumi MINEKAWA
(use	e as many shee	ts as necessar	y)	Art Unit	Unknown
				Examiner Name	Unknown
Sheet	2	of	2	Attorney Docket Number	Q91103

	U.S. PATENT DOCUMENTS							
		Document Nur	nber					
Examiner Initials*	Cite No.1	Number	Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document			
		US						

FOREIGN PATENT DOCUMENTS								
Examiner	Cite	e Foreign Patent Document		Publication Date	Name of Patentee or			
Initials*	No.1	Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation <sup>6</sup>	
1				<u> </u>				

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
	(14)	Fujitsu Ltd., "PRESS RELEASE LAMP-ho no tameno Senyo Primer Sekkei Shien Service o Web de Teikyo LAMP-ho Seihin Hanbai no eMarket Place mo Unyo Kaishi.", [online], May 16, 2002, [retrieved on August 3, 2004], Retrieved from the Internet: <url: 05="" 16-1.html="" 2002="" http:="" jp="" news="" pr.fujitsu.com=""></url:>	
	(15)	H. T. C. Thai, et al., "Development and Evaluation of a Novel Loop-Mediated Isothermal Amplification Method for Rapid Detection of Severe Acute Respiratory Syndrome Coronavirus", Journal of Clinical Microbiology, May 2004, Vol. 42, No. 5, pp. 1956-1961	
	(16)	B. ZHOU, et al., "Identification and molecular cloning and sequence analysis of a novel coronavirus from patients with SARS by RT-PCR", Chinese J. Exp. Clin. Virol., (June, 2003), Vol. 17, No. 2, pages 137-139, (abstract)	Abstract
	(17)	L. L. M. POON, et al., "Rapid Detection of Severe Acute Respiratory Syndrome (SARS) Coronavirus by a Loop-Mediated Isothermal Amplification Assay., Clinical Chemistry, (June 28, 2004), Vol. 50, No. 6, pp. 1050 to 1052	
	(18)	Teruo KIRIKAE, "Current Situation of SARS corona virus test methods and future prospects", Antibiotics & Chemotherapy, (December, 2003), Vol. 20, No. 1, pp. 63-69	Abstract

Examiner Signature /Christopher Babic/	Date Considered	04/14/2008
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CB/

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<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached.